Internal Memorandum

TO: Ed Luce, Quality Systems Specialist

FROM: Mary Celotti, Laboratory Director

DATE: February 24, 2010

RE: Request for Investigation – Quality Aspects of the Alcohol Program

Based on our discussions, listed below are the areas that should be addressed in your investigation:

1.) Review of Record-keeping practices in the DataMaster Breath Testing equipment maintenance/repair area. This should also include a review of the process for documenting, reviewing and filing of the paperwork. Suggestions for improving the record-keeping processes should be noted if applicable.

2.) Review of Standard Operating Procedures (SOPs) for calibrating, maintaining and repairing the DataMaster instruments: Specifically, do the SOPSs exist and include reference to:
   a. Repeatedly running the simulator solution until the instrument passes
   b. Keep replacing parts until the instrument work again
   c. Adding Acetone to the interference solution to pass the instrument
   d. Raising the temperature of a simulator when it's not out of range in order to pass the instrument
   e. Neglecting to perform suck-back tests on instruments with broken one-way valves in order to pass the instrument

3.) Review of Instrument Technical Support Inquiries to determine if the above have occurred and number of instances:
   a. Repeatedly running the simulator solution until the instrument passes
   b. Keep replacing parts until the instrument work again
   c. Adding Acetone to the interference solution
   d. Raising the temperature of a simulator when it's not out of range
   e. Neglecting to perform suck-back tests on instruments with broken one-way valves

4.) Review of Instrument Warranty and Part Ordering Process to Determine if Additional Parts for Older Instruments Are Being Ordered Under Newer Instrument Serial Numbers (for no charge).

5.) Determine with NPAS, whether NPAS Demo model can be used for parts

6.) Washington County Instruments: 1.) Determine if installation of "insulation" on simulator (Montpelier DMT) is an ethical issue 2.) Determine if DMT instruments with simulator vapor readings biased low, need to be pulled and recalibrated. Determine if instruments with identical issues in other counties, were pulled and recalibrated (consistency of practice).

Vermont Department of Health Laboratory

Memo

To: Mary–Stella Celotti, Laboratory Director

From: Edmond P. Luce, Laboratory Ethics & Compliance Officer

CC: Robert Drawbaugh, Toxicology Program Chief

Date: July 29, 2010

Re: Investigation of DataMaster Processes in Franklin County vs. Washington County

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This investigation is to determine the consistency of practices across the DataMasters installed in Franklin County and Washington County and to review these practices and related processes against allegations of unethical conduct.

The observations of this investigation are as follows:

1. For the Franklin County DataMasters, only the Franklin County Sheriffs Office Instrument and the Grand Isle Sheriffs Office Instrument showed TSIs initiated for issues related to low Simulator Solution Concentrations. Each DataMaster had two TSIs initiated for this issue.

    a. The Franklin County Sheriffs Office TSIs were both resolved as follows; one with an on-site visit and after review of Simulator Solution Change protocol with the instrument supervisor and the other was resolved in-house after the adjustment of instrument parameters (lamp & cooler) back into specifications.

    b. The Grand Isle Sheriffs Office TSIs were both resolved on-site; one was resolved after the correct Simulator Solution information was used by the instrument supervisor and the other was resolved after the repair of leaks in the Simulator Jar.

2. All other TSIs for the Franklin County DataMasters were for instrument related issues: including, Pump Errors, Blank Screens, Detector Voltage Issues, Instrument Room Renovations and failure of the Suck-Back Test at Installation.

3. For the Washington County DataMasters, four of the six instruments had TSIs initiated for issues related to low Simulator Solution Concentrations.

    a. The Barre Police Department single TSI was resolved on-site after adjustment of Simulator Temperature closer to specifications.

    b. The Berlin Police Department single TSI was resolved on-site after instrument parameters were confirmed to be within specifications.

    c. The Middlesex VT State Police single TSI was resolved on-site after instrument parameters were confirmed to be within specifications.

    d. The Montpelier Police Department two TSIs were both resolved on-site. The first one was resolved by closing a HVAC vent blowing on the Simulator Jar and the second

was resolved by insulating the Simulator Jar with foam packing material. This insulation was removed approximately two months later.

4. The other two TSIs for the Washington County DataMasters were for instrument issues; one for Touch-Screen issues and the other for the temperature monitoring not being turned on at installation.

After reviewing and comparing the DataMaster processes for these two installation batches, there appears to be no faults in the actions taken to maintain these instruments.

5. This investigator does not believe the installation of insulation on the Simulator jar on the Montpelier Police Department DataMaster presents an ethical issue. Two TSIs documented this process and both included documentation of what was done and the rationale behind it. The first TSI showed resolution after the HVAC vent was closed and this lead to the logical next step of insulating the Simulator jar to resolve the second TSI. There was no malicious intent indicated and these processes are a part of troubleshooting DataMaster issues.

6. Investigation of the failure to perform suck-back tests is not possible as there is no instrument produced documentation when this test is done; however, the DataMaster would not proceed with Diagnostic Testing if this portion of the test was not performed.

7. Review of Standard Operating Procedures (SOP) related to these processes indicates that there are SOPs available for the Calibration & Certification of these DataMasters; including Installation. There are no SOPs for the Maintenance & Repair portion of these processes. The review of TSIs leads to the conclusion that the processes used to resolve DataMaster TSIs are an evolving process and the allegation of unethical practices is inappropriate and unwarranted.

8. The DataMaster Warranty and the ordering procedures of parts for these DataMasters were reviewed and no faults or unethical practices were found in these processes as confirmed by a letter from the instrument manufacturer, National Patent Analytical Systems Inc., dated March 15th, 2010.

9. The review of the record keeping practices throughout this investigation indicates that the Program is doing it's best to maintain complete and accurate records. The records that were available were well organized and accessible. There were a few minor deficiencies noted and these will be shared with the Program at a later date and suggestions for improvements will be discuss at that time.

This investigator concludes that there have not been any unethical practices demonstrated during this lengthy and through investigation. (Reference Memo from the Laboratory Director to the Quality Systems Specialist dated February 24th, 2010.)

1.0 Purpose of this Policy:

It shall be the policy of the Vermont Department of Health Laboratory to conduct all business with integrity and in an ethical manner; and in accordance with all applicable laws, rules, and regulations. It is a basic and expected responsibility of each laboratory employee and supervisor to hold to the highest ethical standard of professional conduct in the performance of all duties.

2.0 Responsibility:

All Vermont Department of Health Laboratory staff are charged with the public's trust; therefore, all laboratory staff must always exhibit a commitment to integrity and high ethical standards. All employees of Vermont Department of Health Laboratory have an ethical and legal responsibility to produce data that is accurate, precise, of known documented quality and legally defensible.

The Vermont Department of Human Resources has a general policy that is a guide for employee conduct; this policy is attached as Appendix C "Vermont Department of Human Resources, Number 5.6, Employee Conduct".

The Public Health Quality Systems Specialist will be responsible for the stewardship of this policy and will report directly to the Laboratory Director. The Public Health Quality Systems Specialist will also be known as the Ethics and Compliance Officer for the purpose of this policy.

3.0 Precautions:

Violations of this policy or failure to report violations of this policy will subject an employee to disciplinary action, including possible termination.

4.0 Procedure Steps

4.1 Definitions

4.1.1 Ethics - a set of moral principles or values; the code dealing with what is right and wrong; behavior that conforms to accepted professional practices.

4.2 A laboratory ethics committee will be comprised of laboratory employees from each program who have participated in at least one business ethics and data integrity training.

4.2.1 Quarterly meetings will be held January, April, July, and October.

4.2.2 The Quality Systems Specialist will facilitate these meetings, and meeting minutes will be taken by the Administrative Assistant B.

4.2.3 Ethical discussions will also be encouraged at program staff meetings.

4.3 All laboratory employees must report (verbally or in writing) any suspected unethical behaviors or activities to one of the following laboratory management personal:

4.3.1 Mary Celotti, Laboratory Director

4.3.2 Edmond Luce, Public Health Quality Systems Specialists

4.3.3 Eunice Froeliger, Microbiology Program Chief

4.3.4 Bob Drawbaugh, Toxicology Program Chief

4.3.5 George Mills, Environmental Chemistry Program Chief

4.4 Unethical situations may also be reported anonymously by placing an unsigned letter (preferably from Word) in a pink envelope, and depositing this in the locked

wooden box located next to the mailboxes. The locked box will be checked weekly by the Quality Systems Specialist.

4.5 Each report of unethical behavior will be investigated by members of the ethics committee and/or by management; including the Ethics and Compliance Officer who will make a summary report to the Laboratory Director. The summary report will also be provided to the individual who raised the issue, if known.

4.5.1 If the situation warrants disciplinary action, then management will be responsible for involving the Department of Personnel.

4.5.2 If the situation is beyond the scope laboratory personnel to investigate, then an outside auditor may be engaged.

4.6 Procedure and Guidance for Recalling Data

4.6.1 If incorrect information is found on any report to laboratory customers, then an amended report must be sent to the customer with an explanation for the amended report in the comments section (and the customer will be asked to destroy the original report). The report status field on the report must indicate "Amended", and the process must be documented using the form ADMIN 917 found in document control.

4.6.2 If any of the incorrect reports have been sent to a second submitter or another agency, then these will need to be amended as well.

4.6.3 A corrective action must be filed each time an amended report is sent.

4.7 Internal and External Monitoring Systems

4.7.1 Compliance with this policy will be monitored through the following procedures:

4.7.1.1 Data review and validation;
4.7.1.2 Internal program or procedure audits;
4.7.1.3 External audits by an accrediting authority;
4.7.1.4 Proficiency sample testing;
4.7.1.5 Review of data entry;
4.7.1.6 Amended reports can be queried through the Laboratory Information Tracking System (LITS) in each testing module; and
4.7.1.7 Corrective Action summaries.

5.0 Emergency or High Priority Situations – Unethical activities and improper laboratory practices constitute an emergency situation. Improper laboratory practices include the following, but are not limited to:

5.1 Artificially fabricating or falsifying data – making up data.
5.2 Improper calibration – deviations from the SOP calibration procedure.
5.3 Misrepresenting quality control data.
5.4 Data file substitution – using previous calibration data or changing sample ID's.
5.5 Improper alterations of analytical conditions – using different analytical conditions for sample analysis than used for calibration.
5.6 Software manipulations – removal of operational codes to hide manipulations, inappropriate background subtraction, or adjusting the baseline.
5.7 Concealment of known problems – concealing a known analytical or sample problem; failing to disclose a known unethical behavior or action from laboratory management.

6.0 Quality Criteria and Corrective Action

6.1 A corrective action report must be filed if the investigation of the report of an unethical behavior precipitates the need for a change to the laboratory's business practices or analytical procedures, or if amended reports are sent.

6.2 Annual ethics training will be provided and documented in the employees' training files located in room #137.

7.0 Preventative Maintenance and Backup Procedures – not applicable

8.0 References

8.1 "Preventing Improper Laboratory Practices" © 2005, Advanced Systems, Inc

8.2 "Guidance Document for Applicants to the Environmental Laboratory Data: Integrity Initiative Program", the Data Integrity Committee of the Environmental Sciences Section of the American Council of Independent Laboratories, October 2003.

1.0 Purpose of this Policy:

It shall be the policy of the Vermont Department of Health Laboratory to conduct all business with integrity and in an ethical manner; and in accordance with all applicable laws, rules, and regulations. It is a basic and expected responsibility of each laboratory employee and supervisor to hold to the highest ethical standard of professional conduct in the performance of all duties.

2.0 Responsibility:

All Vermont Department of Health Laboratory staff are charged with the public's trust; therefore, all laboratory staff must always exhibit a commitment to integrity and high ethical standards. All employees of Vermont Department of Health Laboratory have an ethical and legal responsibility to produce data that is accurate, precise, of known documented quality and legally defensible.

The Vermont Department of Health Laboratory Management Team is responsible for advocating and promoting an environment that is conducive to good laboratory practices; including, ethical behavior and the highest level of data integrity.

The Public Health Quality Systems Specialist will be responsible for the stewardship of this policy and will report directly to the Laboratory Director. The Public Health Quality Systems Specialist will also be known as the Ethics and Compliance Officer for the purpose of this policy.

The Vermont Department of Human Resources has a general policy that is a guide for employee conduct; this policy is attached to the VDHL Quality Systems Manual as Appendix C "Vermont Department of Human Resources, Number 5.6, Employee Conduct".

3.0 Precautions:

Violations of this policy or failure to report violations of this policy will subject an employee to disciplinary action, including possible termination.

Laboratory personnel must remain free of commercial or financial pressure which might influence their technical judgment.

4.0 Procedure Steps

4.1 Definitions

4.1.1 Ethics - a set of moral principles or values; the principles of conduct governing what is right and wrong; behavior that conforms to accepted professional practices.

4.1.2 Integrity - adherence to moral and ethical principles; soundness of moral character; honesty.

4.1.3 Laboratory Fraud - The deliberate falsification of analytical data or quality control results, where failed methods and contractual requirements are made to appear acceptable.

4.2 All laboratory employees must report (verbally or in writing) any suspected unethical behaviors or activities to one of the following laboratory management personnel:

4.2.1 Mary Celotti, Laboratory Director (ext – 7570)

4.2.2 Edmond Luce, Public Health Quality Systems Specialist (ext – 7637)

4.2.3 Eunice Froeliger, Microbiology Program Chief (ext – 7629)

4.2.4 George Mills, Environmental Chemistry Program Chief (ext – 7612)

4.3 Unethical situations may also be reported anonymously by placing an unsigned letter (preferably from WORD) in an envelope, and depositing this in the locked wooden box located next to the mailboxes. The locked box will be checked weekly by the Quality Systems Specialist.

4.4 Each report of unethical behavior will be investigated by members of the Laboratory Management Team; including, at least, the Ethics and Compliance Officer who will make a summary report to the Laboratory Director. The investigation shall be documented where appropriate and include any related supporting data. The summary report(s) and supporting documentation shall be maintained in the locked filing cabinet in room # 137. Documentation shall be maintained for a minimum of five years or for the timeframe dictated by the data associated with the investigation.

4.4.1 If the situation is beyond the scope of laboratory personnel to investigate, then an outside investigator may be engaged.

4.4.2 If the situation warrants disciplinary action, then the Laboratory Director will be responsible for involving the Department of Personnel.

4.5 The findings of the investigation will be reviewed or shared with the individual(s) who raised the issue, if known. Each meeting shall be documented.

4.6 **Procedure and Guidance for Recalling Data**

4.6.1 If incorrect information is found on any report to laboratory customers, then an amended report must be sent to the customer with an explanation for the amended report in the comments section (and the customer will be asked to destroy the original report). The report must indicate that it is "Amended", and the process must be documented using the "Amended Report Documentation" form (ADMIN 917).

4.6.2 If any of the incorrect reports have been sent to a second submitter or another agency, then these reports will need to be amended as well.

4.6.3 A corrective action must be filed whenever data is recalled.

4.7 **Internal and External Monitoring Systems**

4.7.1 Compliance with this policy will be monitored through the following procedures:

4.7.1.1 Data review and validation;

4.7.1.2 Internal program or procedure audits;

4.7.1.3 External audits by an accrediting authority;

4.7.1.4 Proficiency sample testing;

4.7.1.5 Review of data entry;

4.7.1.6 Amended reports can be queried through the Laboratory Information Management System (LIMS) in each testing module; and

4.7.1.7 Corrective Action summaries.

5.0 **Emergency or High Priority Situations** – Unethical activities and improper laboratory practices constitute an emergency situation. Improper laboratory practices include the following, but are not limited to:

5.1 Artificially fabricating or falsifying data – making up data.

5.2 Improper calibration – deviations from the SOP calibration procedure.

5.3 Misrepresenting quality control data.

5.4 Data file substitution – using previous calibration data or changing sample ID's.

5.5 Improper alterations of analytical conditions – using different analytical conditions for sample analysis than used for calibration.

5.6 Software manipulations – removal of operational codes to hide manipulations, inappropriate background subtraction, or adjusting the baseline.

5.7 Concealment of known problems – concealing a known analytical or sample problem; failing to disclose a known unethical behavior or action from laboratory management.

6.0 Quality Criteria and Corrective Action

6.1 A corrective action report must be filed if the investigation of the report of an unethical behavior indicates the need for a change to the laboratory's business practices or analytical procedures, or if amended reports are sent.

6.2 Annual ethics training will be provided and documented in the employees' training files located in room #137.

6.2.1 Training documentation shall include the topics covered during the training.

6.2.2 An "Employee Sign-Off Statement" (ADMIN 933) shall be completed as part of training and when this policy is revised.

7.0 Preventative Maintenance and Backup Procedures – not applicable

8.0 References

8.1 "Preventing Improper Laboratory Practices" © 2005, Advanced Systems, Inc

8.2 "Guidance Document for Applicants to the Environmental Laboratory Data Integrity Initiative Program", the Data Integrity Committee of the Environmental Sciences Section of the American Council of Independent Laboratories, October 2003.

8.3 Dictionary.com

8.4 ADMIN 917 – VDHL Amended Report Documentation.

8.5 ADMIN 933 – VDHL Employee Sign-Off Statement.